

COVID-19 Therapeutics Information Brief

April 20, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be May 4, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund
- Renal Packaging for Paxlovid for Patients with low eGFR
- Test to Treat Program
- Extended Expiration Dates on Sotrovimab and Paxlovid
- Guidelines for Product Return
- Sotrovimab is NO Longer Authorized to Treat COVID-19 Vaccine in any U.S. Region
- Evusheld Fact Sheet Updated
- Sotrovimab Effectiveness Against Omicron Subvariant BA.2
- Return of bam/ete and REGEN-COV NOT Recommended
- CMS Updates: Coding for 600 mg Evusheld
- CMS Updates Codes for Bebtelovimab and Remdesivir
- Reporting Evusheld Doses in HPOp
- Allocation Cadence Changes for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Therapeutic Reporting Reminder
- Reporting Wastage Guidance
- Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- COVID-19 Therapeutics Information Resources

HRSA COVID-19 Uninsured Program and HRSA COVID-19 Coverage Assistance Fund

The [HRSA Uninsured Program](#) has stopped accepting claims for testing and treatment due to lack of sufficient funds. IDPH has received questions regarding billing patients for the administration or dispensing fee. It is important to remember the Provider Agreement outlines the following:

- **Providers may NOT charge the patient directly for the administration or dispensing of an anti-viral.**
- Healthcare organizations must dispense COVID-19 therapeutics regardless of the therapeutic recipient's coverage status or ability to pay for COVID-19 therapeutics dispensing fees.

- Organizations may seek appropriate reimbursement from a program or plan that covers COVID-19 therapeutics dispensing fees for the therapeutics recipient. Organizations may not seek any reimbursement, including through balance billing, from the therapeutic recipient.
- Organizations may not charge an office visit or other fee if dispensing of the COVID-19 therapeutic is the sole medical service provided.
- Organization may not require additional unrelated medical or other services or purchases as a condition precedent to receive the COVID-19 therapeutic. **The Intent is to have no cost sharing for patients.**

For additional information, see [COVID-19 Uninsured Program Claims Submission Deadline FAQs](#).

Renal Packaging for Paxlovid for Patients with low eGFR

Currently, the Dear HCP Letter endorsed by the FDA, in reference to moderate renal impairment dosing being adjusted to 150 mg nirmatrelvir with 100 mg ritonavir taken twice daily for 5 days states: "Pharmacists should discard the removed tablets per state requirements or local guidelines." It is recommended providers dispose of the medication via the workflows used to dispose of expired or other waste purposes. The HCP letter and Pharmacist Instructions are available at: <https://www.covid19oralrx-hcp.com/resources>

Pfizer estimates in the coming weeks there will be a second ordering option for Paxlovid. This option, with a separate NDC, represents new packaging specific for the renal-impaired with adjusted dosing. This new option replaces the current sticker method currently used.

Test to Treat Program

The Biden-Harris Administration launched a new nationwide Test to Treat initiative in March to give individuals an important way to quickly access free lifesaving treatment for COVID-19. The recently launched [Test to Treat program](#) supports this priority effort by creating an additional pathway for fast access to lifesaving COVID-19 treatments.



The federally managed Test to Treat program will focus on Federal Retail Pharmacy Therapeutic Program (FRPTP) partners and associated sites; all other sites will be managed by the state and receive state distributions from the weekly state allocation.

The following considerations should be taken by healthcare providers interested in participating in the Test to Treat Program:

- Provide/offer comprehensive end-to-end test and treat services to support a seamless patient experience:
 - COVID-19 testing on-site (or evaluation of at-home testing)

C19 Therapeutics Call Center: (515) 281-7317 | C19Therapeutics@idph.iowa.gov

- Linkage to a clinical evaluation by licensed healthcare provider after positive result to provide prescription when appropriate
- Co-located or affiliated pharmacy able to readily dispense medication to eligible patient's
 - Provide services to all individuals, regardless of insurance status
 - Accept new patients for priority same-day or next-day visit for COVID-19 services

Healthcare providers interested in participating in the Test to Treat Program should contact the COVID-19 Therapeutics Call Center at: C19Therapeutics@idph.iowa.gov or (515) 281-7317.

Extended Expiration Dates on Sotrovimab and Paxlovid

The shelf life of some lots of Paxlovid and Sotrovimab has been extended. The Food and Drug Administration (FDA) authorized the change for certain lots if they have been stored properly.

Drug Name	Lot Number	Extended Expiration Date
Sotrovimab	658W	08-2022
	XV6W, Y74D, JP9Y, 287F	10-2022
	287X, 432U, 433C, BX3T	11-2022
	9W8S, A39T	03-2023
	BD8F, BC9P, C86N, CC3D, CK9V, D74S	04-2023
	J23C, JJ7J, J67D	06-2023
	MJ8W, ME3Y, MJ8X, ME3Y, NM9X, NM6J, NX3P, PK8J	07-2023
	RM3K, S63E, R97L, S94Y, TE4L	08-2023
Paxlovid	FL4516, FL4517, FR7229	Initial 3 lots were extended from 07/31 to 10/31/2022
	FR9088	4th lot extended from 8/31 to 11/03/2022

Guidelines for Product Return

All therapeutic products are property of the United States Government and must be used in accordance with EUA guidance. Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S. Any returned product will be destroyed, as product integrity cannot be verified. Non-expired products should not be destroyed. Any returned product needs to be quantified by the United States Government.

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
 - Long-term utility of authorized mAb products is expected
 - After consultation with the IDPH COVID-19 Therapeutics Call Center, if undamaged product needs to be returned, follow the below instructions:
 - For bam and bam/ete, see The Lilly Return Goods Procedure, detailed guidance can be found at: <https://www.lillytrade.com/>
 - For REGEN-COV, call 844-734-6643
 - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's standard operating procedures
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Sotrovimab is NO Longer Authorized to Treat COVID-19 in any U.S. Region

As of 04/05/2022, the [FDA](#) has updated the Sotrovimab [Emergency Use Authorization](#) stating **Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases caused by the Omicron BA.2 sub-variant.** FDA will continue to monitor BA.2 in all U.S. regions and will provide follow-up communication when appropriate.

The [Centers for Disease Control and Prevention \(CDC\) Nowcast data](#) from April 5, 2022, estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services (HHS) U.S. regions. Data included in the [health care provider fact sheet](#) show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

Health care providers should use [other approved or authorized products](#) as they choose appropriate treatment options for patients. Currently authorized alternative treatments are available for distribution. These include, Paxlovid (an oral antiviral treatment) and molnupiravir (an alternative oral antiviral for patients for which Paxlovid is not appropriate or accessible). Additionally, bebtelovimab is an alternative monoclonal antibody therapy that is currently authorized and available for distribution. Based on similar in vitro assay data currently available, these products are likely to retain activity against the BA.2 variant.

Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody and oral antiviral therapy available under an [EUA](#) for details regarding specific variants and resistance. Healthcare providers should also refer to the CDC website (<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html>) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

- [COVID-19 Therapeutics Clinical Decision Aids](#)
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Evusheld Fact Sheet Updated

April 1, 2022, the FDA updated the [Evusheld \(tixagevimab co-packaged with cilgavimab\) fact sheet](#) and [frequently asked questions](#) with updated dosing information for patients who had already received the

previously authorized initial dose (150 mg of tixagevimab and 150 mg of cilgavimab). These patients should receive an additional Evusheld dose as soon as possible, with the dose based on the following criteria:

- If the patient received their initial dose less than or equal to 3 months ago, the patient should receive a dose of 150 mg of tixagevimab and 150 mg of cilgavimab.
- If the patient received their initial dose longer than 3 months ago, the patient should receive a dose of 300 mg of tixagevimab and 300 mg of cilgavimab.

It is important to clinically monitor individuals for one hour following an injection of Evusheld. This guidance applies to patients returning for a booster dose. The [FDA Fact Sheet for Healthcare Providers](#) states, “Clinically monitor individuals after injections and observe for at least 1 hour.”

Return of bam/ete and REGEN-COV **NOT Recommended**

Product return of bam/ete and REGEN-COV is **NOT** recommended as any returned product has to be destroyed. The COVID-19 environment remains dynamic and these products may be effective against future variants. Current supplies of bamlanivimab plus etesevimab and Regeneron’s casirivimab plus imdevimab (REGEN-COV) should be retained by healthcare providers for potential use for other COVID variants. If healthcare providers have storage concerns or challenges, consider transferring products to another location/site in the region or health system.

If product must be returned, please follow the guidance below:

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- For bam/ete, see The Lilly Return Goods Procedure; detailed guidance can be found at: <https://www.trade.lilly.com/assets/pdf/lilly-product-return-procedure.pdf>
- For REGEN-COV, call 844-734-6643
- Note: Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's SOP

As doses of bam/ete expire, all providers should check with the manufacturer prior to disposing of the product given the possibility of extended expiration dates. After verification, expired doses should be disposed of in accordance with the facility’s standard operating procedures on medication disposal.

CMS Updates Codes for 600 mg Evusheld

CMS released the new product code updates for Evusheld.

- New product code for 600 mg dosing regimen of Evusheld (Q0221)
- Product code effective back to the date of the FDA EUA update (Feb 24, 2022)
- Original product code of Q0220 (300 mg) still effective and can be used for “catch-up” doses

Resources

- [CMS COVID-19 Monoclonal Antibodies Toolkit](#)
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CMS Updates Codes for Bebtelovimab and Remdesivir

CMS released the following new codes for Bebtelovimab and Remdesivir effective February 11, 2022.

Q0222

- Long descriptor: Injection, bebtelovimab, 175 mg
- Short descriptor: Bebtelovimab 175

M0222

- Long Descriptor: IV injection, bebtelovimab, includes injection and post administration monitoring
- Short Descriptor: Bebtelovimab injection

M0223

- Long Descriptor: Intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider based to the hospital during the covid-19 public health emergency
- Short Descriptor: Bebtelovimab injection home

Resources

- [CMS COVID-19 Monoclonal Antibodies Toolkit](#)
 - [Updated FAQs – Payment/Coding for Veklury \(Remdesivir\)](#) (Pg 146/Question 30)
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Reporting Evusheld Doses in HPoP

Evusheld now should be administered as an initial dose of 600 mg. Individuals who already received the previously authorized initial 300 mg dose should receive a second Evusheld dose as soon as possible.

Reporting doses of Evusheld in HPoP: Healthcare providers are required to report on-hand and usage data of Evusheld **daily** in HPoP.

- Report on-hand inventory based on the number of 300 mg cartons.
- Healthcare providers should not edit Evusheld inventory in HPOP to account for the change in the initial dose. Regardless of the Evusheld dose(mg) administered, a carton or “dose” is 300 mg.
- The initial “dose” administered is 600mg or two 300mg cartons. For the purpose of reporting in HPoP, healthcare providers should report by numbers of cartons. Two cartons administered to a patient would be reported as two “doses” given.
- The catch up “dose” is 300mg or one carton. For the purpose of reporting in HPoP, report by numbers of cartons. One carton administered for a catch up dose would be reported as one “dose” given.

Evusheld Resources:

- [Fact Sheet for Healthcare Providers](#)
- [Healthcare Provider Letter](#)
- [Fact Sheet for Patient's, Parents, and Caregivers](#)

As part of the EUA, FDA requires health care providers who prescribe Evusheld to report all medication errors and serious adverse events considered to be potentially related to Evusheld through FDA's [MedWatch Adverse Event Reporting program](#). Providers can complete and submit the report [online](#); or download and complete the form, then submit it via fax at 1-800-FDA-0178.

Please contact C19therapeutics@idph.iowa.gov, with questions about HPoP.

Allocations Cadence Changes for Monoclonal Antibodies, PReP Treatment and Antivirals

Antivirals will shift to a weekly allocation cycle. This will align with the weekly allocation cadence for monoclonal antibodies (Bebtelovimab and sotrovimab) and the pre-exposure prophylaxis treatment (Evusheld). The ordering cadence will be as follows:

- Allocation Survey Sent - Monday
 - Allocation Survey Due Back to IDPH - Tuesday at 4:00pm
 - Allocation Ordered in Federal System - Thursday
 - Allocation Amount Notification from IDPH to healthcare providers - Thursday
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Therapeutic Reporting Reminder

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **daily** in HPoP.
- Reporting should include product doses utilized since the last report date
- Reporting **IS NOT** a cumulative total of all doses utilized to date
- Please contact C19therapeutics@idph.iowa.gov for assistance with HPoP

Oracle HPoP - Provider Portal

Demo Provider 20 : Therapeutic

TX-HHS-171844 (03/29/2022 10:53) PROCESSING

Total Order Lines: 1

Load more...

Therapeutic Inventory

Courses Administered and Available (since last reported) Wastage Transfers

Courses Administered and Available (since last reported) Edit History Save Therapeutic Courses

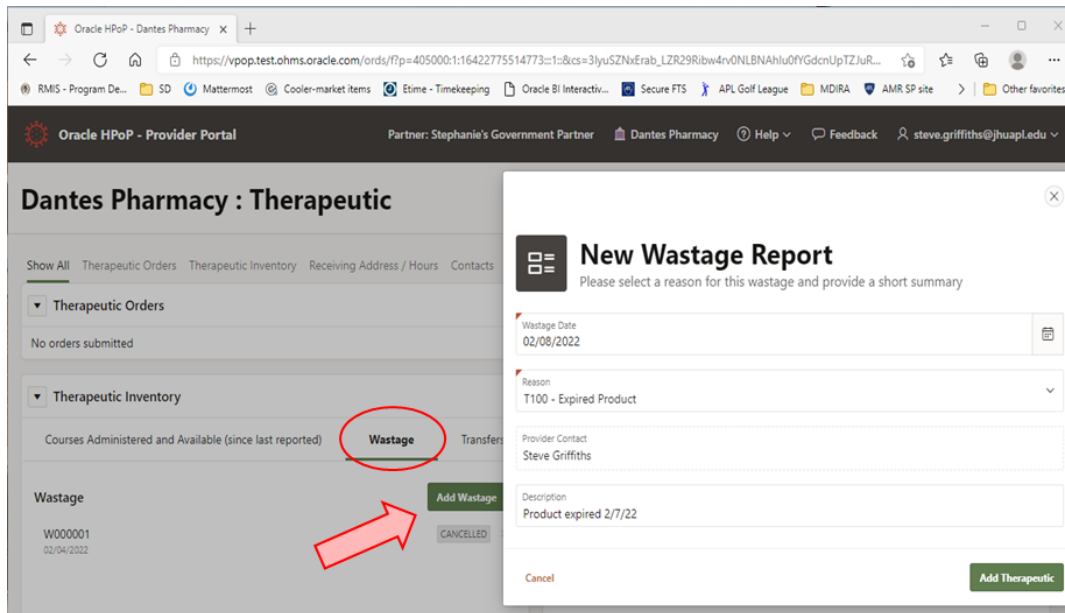
Therapeutic	Courses Administered	Courses Available	History
Bebtelovimab (0002-7589-01)			5:5 on 03/17 by STEVEN.GRIFFITHS@HHS.GOV
Evusheld (0310-7442-02)	3	21	10:10 on 02/28 by KEVIN.CROPPER@HHS.GOV
Lagevrio (molnupiravir) (0006-5055-06)			5:25 on 04/04 by STEVEN.GRIFFITHS@HHS.GOV
Paxlovid (0069-1085-30)			2:18 on 04/04 by STEVEN.GRIFFITHS@HHS.GOV

i For Administered and Available please enter values for today and not cumulative values. Please note that some Therapeutics may not be displayed in Inventory.

Reporting Wastage Guidance

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. **Wastage will be reported for all therapeutic products except Sotrovimab.** The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green “Add Wastage” button. A blank report appears.
- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
 - A provider contact may be chosen, or is predetermined.
 - A description can be added.
- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



Allocations Threshold Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

Iowa Statewide Allocations Threshold Remaining for the week Monday, April 4, 2022 - Sunday, April 10, 2022			
mAbs	Oral AVs		PrEP
Bebtelovimab	Molnupiravir (Lagevrio)	Paxlovid	EVUSHELD
160 courses	384 courses	960 courses	1848 doses (monthly allocation)

- The minimum order quantity for Molupiravir is 24 courses.
- **Allocations will not include sotrovimab, bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a [COVID-19 Therapeutics locator](#).

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center** - IDPH has established a COVID-19 Therapeutics Call Center. To reach the COVID-19 Therapeutics Call Center, call **515-281-7317**.

- **COVID-19 Therapeutics Email** - IDPH has set up a COVID-19 Therapeutics Email to respond specifically to questions from healthcare providers regarding COVID-19 therapeutics. Therapeutic questions can be emailed to: C19Therapeutics@idph.iowa.gov
 - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **[COVID-19 Therapeutics Table](#)**- IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.